

**CALIFORNIA CHILDREN'S
SERVICES AND GENETICALLY
HANDICAPPED PERSONS
PROGRAMS**

**LOW-PROTEIN THERAPEUTIC
FOODS ORDER PROCESSING
MANUAL**

PURPOSE

To update and simplify the process for ordering medical foods for California Children's Services (CCS) Program and Genetically Handicapped Persons Program (GHPP) beneficiaries with inborn errors of metabolism (IEM).

FOOD AND DRUG ADMINISTRATION DEFINITION OF MEDICAL FOODS

"A food which is formulated to be consumed or administered enterally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."¹

CCS/GHPP BENEFIT

Since July 1, 2000, California has required most health care service plan contracts to provide coverage for the testing and treatment of phenylketonuria (PKU).² This includes formulas and special food products that are part of a diet prescribed by a licensed physician who specializes in the treatment of metabolic disease, provided that the diet is deemed medically necessary to avert the development of serious physical or mental disabilities or to promote normal development or function as a consequence of PKU.³

State statute requires that special food products that must be provided to beneficiaries with PKU have the following characteristics:⁴

- » Must be prescribed consistent with the recommendations and best practices of qualified health professionals with expertise germane to and experience in the treatment and care of IEM.
- » Does not include foods that are naturally low in protein.
- » May include food products specially formulated to have less than one gram of protein per serving.

¹ [Section 5\(b\)\(3\) of the Orphan Drug Act \(21 U.S.C. § 360ee \(b\)\(3\)\)](#)

² [California Code, Health and Safety Code - HSC § 1374.56\(a\)](#)

³ [California Code, Health and Safety Code - HSC § 1374.56\(b\)](#)

⁴ [California Code, Health and Safety Code - HSC § 1374.56\(d\)\(2\)\(A\)](#)

- » Are used in place of normal food products, such as grocery foods, used by the general population.

Special food products are a medical benefit for CCS Program and GHPP beneficiaries with IEM. These programs use the statutory standards for PKU special food products as a guide for IEM generally and provide them to CCS Program and GHPP beneficiaries with any IEM that requires amino acid or protein restriction, and not just to those with PKU.⁵ The CCS Program and GHPP refer to medical foods for the treatment of IEM as low-protein therapeutic foods (LPTF).

LPTF orders are subject to Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit medical necessity standards in that the items ordered must be required to correct or ameliorate health problems posed by the underlying IEM condition.⁶

LPTF are not a pharmacy benefit of the Medi-Cal Program and Medi-Cal Rx does not process claims for medical food; however, medical foods are covered for CCS Program beneficiaries under EPSDT and GHPP under state funding.⁷

Complete details on the medical necessity criteria for LPTF can be found in Numbered Letter 03-0725.⁸

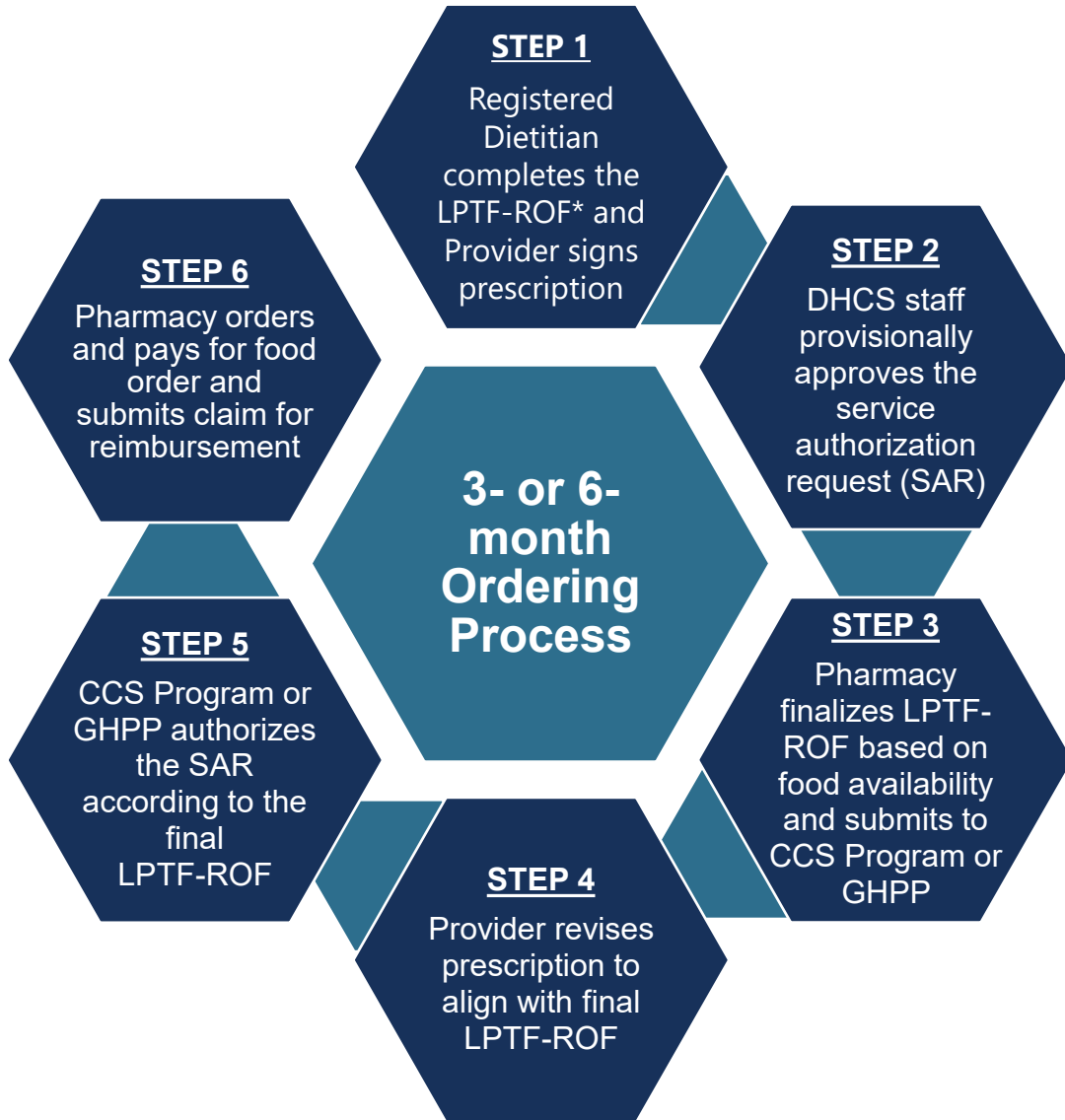
⁵ [California Code, Health and Safety Code - HSC § 1374.56](#)

⁶ [Title XIX of the Social Security Act \(SSA\), § 1905\(r\)\(5\), Title 42 of the United States Code, § 1396d\(r\)](#)

⁷ [Medical Foods are Not a Covered Benefit - Medi-Cal Rx](#)

⁸ California Children's Services Numbered Letter 03-0725

LPTF ORDER PROCESS



**LPTF-ROF: Low-Protein Therapeutic Food Request and Order Form*

ONLINE (INTERNET) LPTF ORDERING

The CCS Program and GHPP utilize several vendors in the United States who specialize in LPTF. LPTF vendors have websites and will fill and ship orders using an online ordering process. The LPTF ordering model utilizes direct online ordering from the LPTF vendor webpage.

Typically, orders are made every three to six months and may involve multiple vendors. Ordering online with direct shipping from the vendor to the beneficiary streamlines the process and ensures that LPTF are delivered quickly. The LPTF vendor is responsible for the quality and delivery of the dry and frozen shipped products. Additionally, the online ordering process creates a virtual store of an extensive variety of LPTF.

ROLES AND RESPONSIBILITIES

The following instructions relate to processes followed for GHPP beneficiaries and for CCS beneficiaries who reside in classic CCS counties. Procedures for CCS Whole Child Model (WCM) managed care plans (MCP) differ based on the plan and require the submission of a Treatment Authorization Request (TAR).

Metabolic Registered Dietitian (RD)

The Metabolic RD clinically manages patients with IEM in consultation with the Medical Genetics physician in a Metabolic special care center (SCC). The team may also include non-physician medical providers (NMP), such as nurse practitioners (NP) and physician assistants (PA). All professionals caring for CCS beneficiaries must be CCS paneled.^{9, 10} The RD develops an LPTF order in consultation with the beneficiary and their caregivers that is individualized to their medical needs and usually support the individual for three to six months. The RD may work with a dietetic technician, registered (DTR) on the administrative aspects of the process. The RD/DTR responsibilities include:

- » Completing the Low-Protein Therapeutic Food Request and Order Form (LPTF-ROF), a formatted Excel spreadsheet, by going to the LPTF vendor website, assessing product availability, and copying the item information, packages ordered (units), and

⁹ [42 U.S.C.A. Section 1396a\(78\)](#)

¹⁰ [California Code, Health and Safety Code - HSC § 123929\(a\)\(2\)](#)

unit pricing to the LPTF-ROF. The RD/DTR also verifies the patient information, “Ship to Physical Address”, and obtaining signature for the LPTF-ROF or separate prescription from the ordering physician or nurse practitioner.

- » Grouping LPTF orders into three- or six- month allotments to minimize shipping charges and optimize efficiency. No individual products can be intermittently ordered unless the product is out of stock initially and the item is determined to be critical for the clinical management of the metabolic condition.
- » Submitting the LPTF-ROF to the pharmacy and CCS Program via fax or email using software that is compliant with the Health Insurance Portability and Accountability Act (HIPAA) and attaching the following to the request:
 - Prescription, if the LPTF-ROF has not been signed by the supervising physician or nurse practitioner;
 - Clinical evaluation with diagnosis completed by the beneficiary’s metabolic physician and dated within twelve months of the order; and
 - Nutrition assessment and treatment plan completed within twelve months of the order by the metabolic RD. This must include recent condition-specific laboratory results and confirmation of beneficiary compliance with the LPTF diet.
- » Working with the provider to update the prescription to align with Program medical necessity alterations or vendor product availability.
- » Ordering substitutions if needed.
- » Maintaining communication with the pharmacy, county, and patient or primary caregivers until the order has been received.
- » Initiating a secondary order for any complete order that contained <75% of the items requested.

CCS Program Staff

LPTF order processing differs by classic county type. Classic Independent counties process LPTF requests and DHCS processes LPTF orders for classic Dependent counties. The beneficiary’s county of residence is responsible for coordinating communication between the provider, the pharmacy, the beneficiary and their primary caregivers. DHCS staff responsibilities include:

- » Verifying the LPTF-ROF, prescription, and recent RD and physician reports have been submitted.

- » Reviewing requested items for medical necessity. When pending the SAR:
 - For Medi-Cal full-scope no share-of-cost beneficiaries, check the EPSDT box.
 - For all other CCS beneficiaries, do not check the EPSDT box.
 - Enter the LPTF HCPCS service code: S9435.
 - Select the category "Medical Foods".
- » If needed, pending a second SAR for any items removed from the original order for lack of medical necessity with a unit value equal to the number of items and deny.
- » To provisionally approve the SAR with a unit value of one (1). A provisional approval appears in CMS Net as status "Approve-Y". It is not an authorization. Rather it signals that the order has been found to meet medical necessity standards and alerts the pharmacy to finalize, submit and pay for the order. As vendor inventory is dynamic, this extra step allows for alignment of the order with product availability. The pharmacy will remove from the final order any food items that are out of stock and upload the final LPTF-ROF to the SAR in CMS Net.
- » If items are out of stock, request from the provider a revised prescription or finalized LPTF-ROF that aligns with the final pharmacy order. This does not require a denial also known as Notice of Action (NOA).
- » To authorize the SAR by updating the following:
 - Enter the final item units into the service line of the SAR.
 - Enter the final negotiated price without a dollar sign (\$) into the service code information section of the SAR.
 - Include in the Special Instructions Text box the total units claimed, and the total reimbursable amount claimed for LPTF.
 - Document the item's units and dollar amount from the peach-colored section of the LPTF-ROF from each vendor into the SAR Special Instructions section.

Example:

3	UNIT(S) -CBF-	10411-PORTABELLA SPINACH RAVIOLI-453G PKG	\$91.08	
5	UNIT(S) -CBF-	10406-PASTA DUETS-MACARONI AND CHEESE-198.4G PKG	\$70.81	
4	UNIT(S) -PKUP-	KMAA1332D-SO DELICIOUS COCONUT MILK CHOCOLATE BEVERAGE GRAB N' GO-8OZ		\$82.50
4	UNIT(S) -PKUP-	KMAA14844-GRAHAM STYLE CRUMBS-300G BOX	\$44.75	
5	UNIT(S) -PKUP-	KMAA1020B-G WASHINGTON'S GOLDEN SEASONING & BROTH-1.1OZ BOX		\$37.19
3	UNIT(S) -PKUP-	KMAA1093-EL NACHO GRANDE CHEESE SAUCE 8 PORTION PACKS-3.5OZ PKS		\$59.81
3	UNIT(S) -PKUP-	KMAA1474CSA-CHAO CHEESE SLICES CREAMY ORIGINAL-7OZ PKG	\$26.06	
1	UNIT(S) -PKUP-	KMAA1345CSC-SO DELICIOUS COCONUT MILK RASPBERRY YOGURT-5.3OZ CUPS		\$23.13
28	IS TOTAL UNITS CLAIMED	TOTAL REIMBURSABLE AMOUNT CLAIMED FOR MEDICAL FOODS IS		\$435.33

- » Send a copy of the SAR authorization and final LPTF-ROF to the pharmacy, RD/DTR, and beneficiary or primary caregivers so that each has a list of the order in transit.
- » Provide a NOA to inform the beneficiary and their primary caregivers of a reduction, modification or denial and include their right to appeal.¹¹

GHPP Staff

GHPP is a statewide health care program for adults with specific genetic disorders, including IEM. LPTF prescriptions are received from Medi-Cal-approved physicians and nurse practitioners. Upon receipt of a LPTF request, prescription with current RD and physician reports, DHCS staff review and authorize them in a manner similar to the CCS process described above.

Pharmacy Provider

The pharmacy must be a Medi-Cal provider in good standing to submit claims to the Medi-Cal Program's fiscal intermediary and must have the ability to open accounts with LPTF vendors. The actual vendor accounts will depend on the foods ordered by the RD/DTR. Pharmacies must first establish payment accounts with the LPTF vendors. Once a pharmacy has an open account, they can order LPTF and arrange shipment directly to the beneficiary or their primary caregivers. The pharmacy provider role is:

- » To receive the LPTF-ROF from the RD/DTR and assess product availability.
- » To receive the provisional SAR approval.
- » To update order quantities and remove any items that are out of stock.
- » To attach the final LPTF-ROF to the SAR. Alert CCS Program staff to work with the provider to revise the prescription to align with the final order. As a reminder:
 - Back orders are not allowed.
 - Substitutions are not required if at least 85% of the total number of ordered products is available. If more than 15% of the order is out of stock, the pharmacist should encourage the provider to prescribe substitutions.
- » To verify shipping address and delivery date because frozen products require an exact date. Arrange shipment of the finalized order directly to the beneficiary

¹¹ [California Code Regulations. Title 22, § 42131 - Written Notice of Action](#)

address. Request that the beneficiary or primary caregivers acknowledge order receipt.

- » Upon notification that the final prescription has been uploaded to the SAR, order products from the vendor's website and pay for them.
- » To complete the LPTF-ROF by recording the ordered quantity amounts on the "third" column in the foods section and attach it to the SAR.
- » If the pharmacy does not receive SAR authorization within 3 business days, contact CCS Program staff to inquire about the order status.
- » To verify beneficiary receipt of the product. If the approved order does not match the items delivered, notify the DHCS staff to modify the SAR and request a final aligned prescription.
- » To submit claim forms with the authorized SAR and payment invoice to Medi-Cal's fiscal intermediary.

POTENTIAL ORDERING PROBLEMS AND SUGGESTED SOLUTIONS

- » LPTF vendors are out of inventory or cannot ship the requested amount of a product.
 - *Suggested Solution:*
 - The pharmacy notifies the Program to update the SAR and to contact prescriber to update the prescription. If the number of unavailable products is more than 15% of the total number of ordered products, the prescriber adds substitutions.
 - If delivery has occurred and more than 25% of the original order was not received or if missing food items are critical to the patient's clinical management, the RD/DTR and prescriber can initiate a secondary order using a new LPTF-ROF and the reason for it within one month of delivery of the primary order.
- » The LPTF item specifications on the LPTF-ROF does not match vendor's product code, cost, or the description on the website.
 - *The Problem:*
 - Similarly named products are available from different vendors.

- Product codes will vary for the same product according to the packaging, e.g., single vs. multi-unit packaging.
- It is the responsibility of the RD/DTR to identify the vendors and to order items with the correct product description, product code, and pricing.
- It is the responsibility of the pharmacy to verify that the vendors, product descriptions, product codes, and pricing on the order are correct and to work with the RD/DTR to resolve issues.
- *Suggested Solution:*
 - The pharmacy must order items from different vendors at the same time to ensure food shipments will be received simultaneously.
 - When reviewing the LPTF-ROF, the pharmacy must make sure to scroll all the way through the form to catch all requested products from various LPTF vendors.
 - Pharmacy, county staff, and RD/DTR work together to follow up and confirm final delivery of all items ordered.
- » Beneficiary or primary caregivers complain about an incomplete order.
 - *Suggested Solution:*
 - The pharmacy must order items from different vendors at the same time so food shipments will be received simultaneously.
 - When reviewing the LPTF-ROF, the pharmacy must make sure to scroll all the way through the form to catch all requested products from various LPTF vendors.
 - Pharmacy, county staff, and RD/DTR work together to follow up and confirm final delivery of all items ordered.
- » Frozen foods are delivered thawed and in poor condition.
 - *Suggested Solution:*
 - Frozen foods are usually shipped on a set day of the week and require the pharmacy and vendor to verify the delivery address and ensure that the beneficiary / primary caregivers are available to receive delivery on the specified date. The RD/DTR may help coordinate with the beneficiary / primary caregivers.

LPTF-ROF

The LPTF-ROF is an Excel spreadsheet that calculates a mark-up for each requested product. This is the Total Cost + % Markup column which is the "5th" column from the left of the order form. The top of the LPTF-ROF lists the necessary beneficiary / primary caregiver, pharmacy, and SCC information which is needed for case management and billing. The form provides hyperlinks to the available LPTF vendors and separate lines to list requested products with the corresponding description and unit cost. The RD/DTR should use the "copy" and "paste" function when transferring information from the LPTF vendor's webpage to the request and order form into the text field of the cell they want the text to appear. For subsequent requests, the RD/DTR can use the "save as" function to save the form for reuse.

Patient:		Name (enter patient name)	Ordering Physician (enter MD name)		
	CIN # (enter patient CIN number if known-optional)		Last Assessment Date for MD & RD (enter last MD/RD assessment date)		
	Patient CCS/GHPP # (enter patient CCS or GHPP #)		Date of Order (enter date)		
	Date of Birth (enter patient birthdate)		# months of food		
	County of Residence (enter patient county of residence)		Registered (enter RD name)		
	Ship To Address (enter patient current ship to address)		Phone # (enter RD phone)		
	Ship To Address is to (confirm if shipping address is to home, work, friend, relative)		Fax # (enter RD fax)		
	Contact Phone # (enter patient's contact phone number)		Email Address (enter RD email address)		
Dispensing Pharmacy:		Name (enter pharmacy's business name)	Special Care Center Name (enter special care center name)		
	Provider NPI # (enter pharmacy's NPI)		Diagnosis and ICD-9 Code (enter diagnosis and dx code)		
	Phone and Fax # (enter phone: fax:)		Pharmacist Email Address (enter pharmacist email address)		
IF THERE ARE INSUFFICIENT ROWS TO ENTER ORDER FOR A SPECIFIC VENDOR, CREATE A SEPARATE SPREADSHEET FOR ADDITIONAL ITEMS AND					
			SPREADSHEET #	OF #	
RD REQUESTED ORDER QTY (# packages or # cases)	UNIT COST (per ordered package or case)	PHY ACTUAL ORDER QTY (# packages or # cases ordered)	RD to Copy and Paste Product Description from Web Site (Include Product Code and specify package size or case size)		
			PHY ACTUAL TOTAL COST + % MARKUP	PHY ACTUAL TOTAL COST	RD ORDER TOTAL COST + % MARKUP
CAMBROOKE FOODS (CBF)			http://www.cambrookefoods.com/		foods
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
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		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00
		Unit(s) -CBF-	\$0.00	\$0.00	\$0.00

		Unit(s) -N/LP-	\$0.00	\$0.00	\$0.00
		Unit(s) -N/LP-	\$0.00	\$0.00	\$0.00
		Unit(s) -N/LP-	\$0.00	\$0.00	\$0.00
		Unit(s) -N/LP-	\$0.00	\$0.00	\$0.00
		Unit(s) -N/LP-	\$0.00	\$0.00	\$0.00
		Unit(s) -N/LP-	\$0.00	\$0.00	\$0.00

PKU PERSPECTIVES (PKUP)		http://www.pkuperspectives.com/			
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		Unit(s) -PKUP-	\$0.00	\$0.00	\$0.00
		Unit(s) -PKUP-	\$0.00	\$0.00	\$0.00
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		Unit(s) -PKUP-	\$0.00	\$0.00	\$0.00

TASTE CONNECTIONS (TC)		http://www.tasteconnections.com/			
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		Unit(s) -TC-	\$0.00	\$0.00	\$0.00
		Unit(s) -TC-	\$0.00	\$0.00	\$0.00
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		Unit(s) -TC-	\$0.00	\$0.00	\$0.00
		Unit(s) -TC-	\$0.00	\$0.00	\$0.00

	RD TOTAL UNITS REQUESTED		is TOTAL UNITS CLAIMED	TOTAL REIMBURSABLE AMOUNT CLAIMED FOR MEDICAL FOODS is	\$0.00	TOTALS THIS ORDER	\$0.00
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INCLUDE WITH THIS FORM AND DATED WITHIN THE LAST 6 MONTHS:

1. A written prescription signed by a CCS paneled or GHPP authorized physician. Physician signature below constitutes a legal prescription.
2. Nutrition assessment and treatment plan by a CCS paneled or GHPP authorized Registered Dietitian (RD) that includes the number of phenylalanine exchanges from low protein foods.
3. Medical history and center evaluation which includes diagnosis, medical condition, and documentation of low protein therapeutic food necessity.

Physician Signature Box				Signature Date	

CA Lic #:	Physician Name (Print):	Telephone#:	NP#:
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CLAIM PROCEDURE

The pharmacist is responsible for paper-billing the completed LPTF order using the CMS 1500 Claim Form.¹² For the one claim line processing:

- » Use the number total for “PHY Actual Order QTY” (Column 3) when completing the CMS 1500 Claim units section (Field 24 G).
- » Use the cost figure in the “Total Cost + % Markup” (Column 5) when completing the CMS 1500 Claim charges section (Field 24 F). Typed claims are preferred, otherwise print clearly and stay within each individual box. See Appendix 1 for detailed and specific instructions for accurately completing claim forms. Additional Medi-Cal billing tips for paper claims can be found at: [Medi-Cal: Billing Tips: Paper Claims](#).
- » Attach the “approved” LPTF-ROF to each claim form.

CMS-1500 Claim Form

Correct completion of the CMS-1500 Claim Form¹³ is critical for prompt and accurate reimbursement from Medi-Cal’s fiscal intermediary. See detailed instructions for completing the CMS-1500 form: [CMS-1500 Tips for Billing \(CMS tips\) \(ca.gov\)](#).

Call Medi-Cal’s fiscal intermediary Help Desk at 800-541-5555 for questions regarding claims.

¹² [Health Insurance Claim Form](#)

¹³ [Health Insurance Claim Form](#)

APPENDIX 1: INSTRUCTIONS FOR ACCURATELY COMPLETING HEALTH INSURANCE CLAIM 1500 FORM¹⁴

Field	Instructions
Top of Claim Form	Print "EPSDT" on the top of the claim form if the patient has full scope, no-share-of-cost Medi-Cal
Fields 1-3	For Field 1, check "Medicaid." Complete the remainder of the patient information. For GHPP clients, leave 1a blank.
Field 4	Leave blank
Fields 5 & 6	Complete with patient information
Fields 7-16	Leave blank
Fields 17	List name of referring provider and use NPI # on 17b
Field 18	Leave blank
Field 19	Note what number claim form out of the series of claim forms for the same patient. Example: 1 of 5
Field 20	Leave blank
Field 21	Complete ICD-9 Code- list same code once only
Field 22	Leave blank
Field 23	Complete SAR # from the "Approved" SAR (This is a 11 digit #). For GHPP claims, leave this field blank; GHPP will code it.
Field 24 A	Complete with order date: Use the same date for Dates of Service " from " and " to ".
Field 24 B	Complete; Place of Service usually is 12
Field 24 C	Leave blank
Field 24 D	Use approved billing code
Field 24 E	Leave blank
Field 24 F	Complete with charge (Total Charge + % Markup) which must exactly match line by line the "Total Reimbursable Amount Claimed" on the "Approved" SAR Special Instructions.
Field 24 G	Complete the number of ordering units which must match the "Total Units Claimed" field on the "Approved" SAR, Special Instructions section.
Field 24 H, I & J	Leave blank
Field 25	Complete
Field 26	Leave blank or pharmacy may use for internal tracking

¹⁴ [Health Insurance Claim Form](#)

Field	Instructions
Fields 27-31	Complete: check "No" in Field 27 and put "0" in Field 29
Field 31	Sign and Date
Field 32	Leave blank
Fields 33 & 33a	Complete
Attach "Approved" SAR	Attach all pages of the "Approved" SAR".

If you have any questions, please email the following:

- » For CCS questions: ISCD-MedicalPolicy@dhcs.ca.gov.
- » For GHPP questions: GHPP@dhcs.ca.gov; or GHPPEligibility@dhcs.ca.gov.
- » For any claims related issues, please call the Telephone Service Center at (800) 541-5555.